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10/787,393	02/27/2004	Tony Mikaer Wahlroos	108306-00024	5309

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EXAMINER
PAGE, BRENT T

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1638	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/787,393	WAHLROOS ET AL.	
	Examiner	Art Unit	
	Brent Page	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-53* is/are pending in the application.

4a) Of the above claim(s) *11,12,15,17,21,22 and 26-52* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,13,14,16,18-20,23-25 and 53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :05/04/2004, 07/16/2004 and 03/14/2007.

DETAILED ACTION

Applicant's election with traverse of Group III and the carrier protein oleosin and the Napin promoter sequence in the reply filed on 03/14/2007 is acknowledged. The traversal is on the grounds that it would not be undue search burden for the Examiner to search oleosin, caleosin, or steroleosin. This is not found persuasive because a search of any one of the above is not sufficient for any of the others, and therefore a search burden exists.

The requirement is still deemed proper and is therefore made FINAL.

Claim 21 reads on non-elected subject matter and is withdrawn by the Examiner. Claims 1-53 are pending. Claims 1-10, 13-14, 16, 18-20, 23-25 and 53 are Examined on the merits in the following office action. Claims 11-12, 15, 17, 21-22 and 26-52 are withdrawn.

Claim Objections

Claims 14, and 19 are objected to because of the following informalities: The claims contain non-elected subject matter. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 recites "a carrier protein having a stable polyamino acid extension and intact biological functions as compared to a corresponding unmodified carrier protein". It is unclear what limitation is intended by Applicant in this claim. An unmodified carrier protein would seem to have "intact biological functions", and therefore there does not seem to be a proper comparison basis for the claim. If there is a difference in the "intact biological function" of the modified carrier protein and the unmodified carrier protein, it is not described in the specification and there is no mention of this difference.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 6-10, 18 and 23-25 rejected under 35 U.S.C. 102(b) as being anticipated by Hoffman (US Patent 5003045).

The claims are broadly drawn to a method for increasing the amino acid content of any tissue or organ of a plant comprising transformation of a plant with a recombinant nucleotide sequence construct comprising regulatory sequences specific for a plant operably linked to a nucleotide sequence encoding a carrier protein fused in frame with a nucleotide sequence encoding any polyamino acid extension that comprises histidine, cysteine, methionine, glycine, lysine, tryptophan, alanine, valine, leucine, isoleucine, praline, phenylalanine, tyrosine, serine, threonine, arginine, aspartate, glutamate, asparagines, glutamate encoding codons or any combination thereof, and wherein transformation of the plants with the construct is selected using a reporter gene; and selecting for stable translation of the polyamino acid extension, wherein the transformation is carried out with microprojectile bombardment or Agrobacterium and the reporter protein is a fluorescent protein selected from the group consisting of green fluorescent protein, red fluorescent protein, beta-glucoronidase, obelin or luciferase.

Hoffman teaches the insertion of 15 amino acid residues including 6 methionines (which constitutes a selected number of optimal codons encoding amino acid sequences for increasing the content of one or more selected amino acids) into the Phaseolus vulgaris phaseolin gene and in frame with the phaseolin gene, and the transformation of tobacco, wherein the construct was expressed in the developing seed tissue of the plant (see Example 3 and Example 8 in particular as well as claims 1-12, for example). Example 3 points out the position where the selected amino acids are inserted. The insertion of

the amino acid encoding nucleotide sequence meets the limitations of the claimed invention as the sequence being fused in frame with the amino acid encoding sequence necessarily is lacking a termination codon since the amino acid encoding nucleic acid is being fused in-frame 5' to the termination codon. Stable transformation of tobacco is reported. The teachings of Hoffman further anticipate claims 6-8 and 23-25 in that, absent evidence to the contrary the construct taught by Hoffman is inherently "obtainable" by the method described in claims 6-8 and 23-25 and would be indistinguishable from a construct obtained differently.

Claims 1, 3, 6, 9-10, 13-14, 16, 18, and 23-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Moloney (US Patent 5650554).

The claims are broadly drawn to a method for increasing the amino acid content of an oil body of a plant comprising transformation of a plant with a recombinant nucleotide sequence construct comprising regulatory sequences specific for a plant operably linked to a nucleotide sequence encoding an oleosin protein fused in frame with a nucleotide sequence encoding any polyamino acid extension that comprises histidine, cysteine, methionine, glycine, lysine, tryptophan, alanine, valine, leucine, isoleucine, praline, phenylalanine, tyrosine, serine, threonine, arginine, aspartate, glutamate, asparagines, glutamate encoding codons or any combination thereof, and wherein transformation of the plants with the construct is selected using a reporter gene wherein the reporter protein is a fluorescent protein selected from the group consisting of green

fluorescent protein, red fluorescent protein, beta-glucoronidase, obelin or luciferase.

Moloney teaches the transformation of Brassica plant with a DNA construct comprising regulatory sequences operably linked with a recombinant fusion protein comprising oleosin linked in reading frame with a recombinant polypeptide wherein the recombinant peptide is targeted to the oil body of the plant and the recombinant polypeptide inherently comprises at least one combination of amino acids described above wherein the reporter protein is beta-glucoronidase (see claims 1-3, 11-12, 22, 25-28 and Tables I-III, for example).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-10, 18-20, 23-25 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoffman (US Patent 5003045) as applied to claims 1, 3, 6-10, 18 and 23-25 above, in view of Patten et al (US patent 6413745, filed on November 27, 2000) further, in view of Puthigae et al (US Patent 6291666, filed

on June 5, 2000) and further, in view of Josefsson et al (1987 The Journal of Biological Chemistry 262: 12196-12201).

The claims are drawn to the method described above wherein the construct with the optimal number of codons allowing stable translation of the polyamino acid extension is selected using a cell free in vitro translation system, and wherein the construct is selected with a transient expression assay wherein a green fluorescent reporter protein is used for detecting expression and wherein the Napin promoter is used.

Hoffman anticipates claims 1, 3, 6-10, 18 and 23-25 as described above.

Hoffman does not teach using a cell free in vitro translation system to select the optimal number of codons, the transient expression assay using the green fluorescent protein or the napin promoter.

All three elements of the claims not taught by Hoffman are well known standard tools and methods taught in the art that are used routinely by those of ordinary skill in the art. The references cited above exemplify these elements.

Patten et al teach the wheat germ in vitro translation system (see Column 21 line 47- Column23 Lines 1-13, for example) used in the claimed invention.

Puthigae et al teach a transient expression assay using a green fluorescent protein for testing the expression of a gene from a DNA construct (see Column 8 line 57-Column 9 line 17, for example).

Josefsson et al teach the napin promoter.

Hoffman teaches a seed storage-specific promoter which is the phaseolin promoter, but in the present invention where a specific tissue is targeted, any

promoter that is specific to the same tissue may be used absent a demonstrated unique result using a particular promoter. Therefore, the use of the napin promoter taught by Josefsson et al, which is also a seed storage specific promoter is merely a design choice that would have been obvious to one of ordinary skill in the art at the time of invention to use in place of the phaseolin promoter to use the method taught by Hoffman.

Similarly, optimization of codons and the testing of the expression of the resulting protein are both routine procedures in the laboratory and it would have been readily available and obvious for one of ordinary skill in the art to optimize the codons using the wheat germ in vitro translation system taught by Patten et al as suggest by Patten et al and it would have been obvious to test expression using a transient expression system utilizing green fluorescent protein as taught and suggested by Puthigae et al.

Given the state of the art and the disclosures by Hoffman, Patten et al, Josefsson et all and Puthigae et al, it would have been obvious to one of ordinary skill in the art to modify the method taught by Hoffman by using the napin promoter in place of the phaseolin promoter and to optimize the codons using the IVT system taught and suggested by Patten et al and to test the expression using a transient expression assay as taught and suggested by Puthigae et al.

Claims 1-10, 13-14, 16, 18-20, 23-25 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moloney (US Patent 5650554) as applied to claims 1, 3, 6, 9-10, 13-14, 16, 18, and 23-25 above, in view of Patten et al (US patent 6413745, filed on November 27, 2000) further, in view of

Puthigae et al (US Patent 6291666, filed on June 5, 2000) and further, in view of Josefsson et al (1987 The Journal of Biological Chemistry 262: 12196-12201).

The claims are drawn to the method described above wherein the construct with the optimal number of codons allowing stable translation of the polyamino acid extension is selected using a cell free in vitro translation system, wherein the construct is selected with a transient expression assay, wherein the transformation is carried out using microprojectile bombardment, wherein the transformation is carried out using an Agrobacterium mediated transformation and wherein the Napin promoter is used.

Moloney anticipates claims 1, 3, 6, 9-10, 13-14, 16, 18, and 23-25 as described above.

Moloney does not teach using a cell free in vitro translation system to select the optimal number of codons, the transient expression assay, the transformation of plants with microprojectile bombardment or Agrobacterium or the napin promoter.

Patten et al teach the wheat germ in vitro translation system (see Column 21 line 47- Column23 Lines 1-13, for example) used in the claimed invention.

Puthigae et al teach a transient expression assayfor testing the expression of a gene from a DNA construct as well as Agrobacterium mediated transformation and incorporates by reference Microprojectile bombardment (see Column 8 line 57-Column 9 line 17, and the first paragraph of the background) for example).

Josefsson et al teach the napin promoter.

All of elements of the claims not taught by Moloney are well known standard tools and methods taught in the art that are used routinely by those of ordinary skill in the art. The references cited above exemplify these elements.

Given the state of the art and the disclosures by Moloney, Patten et al, Josefsson et all and Puthigae et al, it would have been obvious to modify the invention of Moloney at the time of filing to substitute the seed specific napin promoter of Josefsson for the seed specific oleosin promoter taught by Moloney or to substitute a biolistic method of transformation available in the art for an *Agrobacterium* method of transformation; or to select for optimal codon number using a cell free *in vitro* translation system; or to select for optimal codon number or to use a transient assay system to select for a construct. One of ordinary skill in the art would have recognized and appreciated the teachings of Moloney, that a DNA transformation cassette comprising the oleosin promoter and coding region fused in frame to the GUS coding region, when transformed into Brassica, expresses in a stable fashion the oleosin protein fused to the GUS reporter protein in the transformed seeds and targeted to the oil bodies of the seeds, and would have a reasonable expectation of success given the success of Moloney of expressing the oleosin-GUS fusion protein in the oil bodies of Brassica seeds; and where transformation with *Agrobacterium* or using a biolistic method; or substituting one seed specific promoter for another; or selecting for optimal codon number using a cell free *in vitro* translation system; or to use a transient assay system to select for a construct, is an obvious optimization of design parameters absent any evidence of criticality.

No claims are free of the prior art.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brent Page whose telephone number is (571)-272-5914. The examiner can normally be reached on Monday-Friday 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571)-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brent T Page

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